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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,674	11/15/2001	Richard J. Whitley	27373/33716	8665

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/869,674

Applicant(s)

WHITLEY ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 7-13, 15, 17-20, 22, 24-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-5, 7-13, 15, 17-20, 22, 24-31, and 33-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment and the Declaration under 37 CFR 1.121 by Dr. Whitley received on 3/3/06 have been entered. Claims 3, 6, 14, 16, 21, 23, and 32 are canceled. New claim 34 has been added. Claims 1-2, 4-5, 7-13, 15, 17-20, 22, 24-31, and 33-34 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-2, 4, 17, 19-20, 24, 31, and 33 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,379,674 B1 (4/30/02), hereafter referred to as Rabkin et al. is maintained. Applicant's arguments and the Declaration under 37 CFR. 1.121 by Dr. Whitley have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the evidence submitted in the form of a Declaration under 37 CFR. 1.121 by Dr. Whitley demonstrates that the applicant was in possession of the invention prior to the earliest effective filing date of Rabkin et al. Specifically, the applicant's response and the Declaration state that the applicant was in possession of double mutant HSV vectors comprising a coding region for IL-4 or IL-10 prior to August 12, 1997. While the declaratory

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evidence provided, i.e. laboratory notebook pages, demonstrates that in fact the applicant has possession of HSV vectors encoding IL-4 or IL-10 prior to 8/12/97, there is nothing in the notebook pages provided or in the Declaration that suggests that the applicant had possession of the claimed invention, which is a recombinant herpes simplex virus which lacks all or part of both  $\gamma_134.5$  genes and which comprises an expressible **GM-CSF** encoding DNA. While the declaratory evidence establishes that the Rabkin et al. reference could not be used as a 102(e) reference to anticipate HSV vectors encoding IL-4 or IL-10, the instant claims do not read on these embodiments. There is no evidence of record that the applicant contemplated inserting GM-CSF into the HSV vectors disclosed in the laboratory notebook pages. As such, the declaratory evidence does not apply to the actual claimed subject matter in the instant application. As stated in the previous office action, Rabkin et al. teaches mutated HSV viruses which are incapable of expressing a functional  $\gamma_134.5$  gene product and which comprise at least one expressible nucleotide sequence encoding GM-CSF (Rabkin et al., column 3, lines 8-15, column 5, lines 28-41, and **column 8, lines 27-37**). Therefore, applicant's evidence that they were in possession of 2 species of HSV vectors encoding either IL-4 or IL-10 does not overcome the teachings of Rabkin et al. for a completely different species of HSV encoding GM-CSF. Thus, the rejection of record is maintained.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 5, 19, and 22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,379,674 B1 (4/30/02), hereafter referred to as Rabkin et al. in view of U.S. Patent No. 5,328,688 (7/12/94), hereafter referred to as Roizman '688, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the declaratory evidence provided removes Rabkin et al. as an available prior art reference and that the secondary references cannot remedy the deficiencies created by the removal of Rabkin et al. In response, as discussed above, the declaratory evidence does not remove Rabkin et al. as an applicable reference under 102(e) because the declaratory evidence is directed to unclaimed species of immunomodulatory proteins, IL-4 and IL-10, and does not provide evidence that the applicant was in possession of HSV vectors encoding GM-CSF prior the earliest effective filing date of Rabkin et al. Therefore, since Rabkin et al. qualifies as prior art over the claimed species of HSV, the rejection of record stands.

The rejection of pending claims 1, 7-8, 12-13, 15, 18-19, 25-26, 30, and 34 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,379,674 B1 (4/30/02), hereafter referred to as Rabkin et al., in view of Andreansky et al. (1998) Gene Therapy, Vol. 5, 121-130, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the declaratory evidence provided removes Rabkin et al. as an available prior art reference and that the secondary references cannot remedy the deficiencies created by the removal of Rabkin et al. In response, as discussed above, the declaratory evidence does not remove Rabkin et al. as an applicable reference under 102(e) because the declaratory evidence is directed to unclaimed species of immunomodulatory proteins, IL-4 and IL-10, and does not provide evidence that the applicant was in possession of HSV vectors encoding GM-CSF prior the earliest effective filing date of Rabkin et al. Therefore, since Rabkin et al. qualifies as prior art over the claimed species of HSV, the rejection of record stands.

The rejection of claims 1, 9-11, 19, and 27-29 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,379,674 B1 (4/30/02), hereafter referred to as Rabkin et al., in view of U.S. Patent No. 5,641,651 (6/24/97), hereafter referred to as Roizman '651, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the declaratory evidence provided removes Rabkin et al. as an available prior art reference and that the secondary references cannot remedy the deficiencies created by the removal of Rabkin et al. In response, as discussed above, the declaratory evidence does not remove Rabkin et al. as an applicable reference under 102(e) because the declaratory evidence is directed to unclaimed species of immunomodulatory proteins, IL-4 and IL-10, and does not provide evidence that the applicant was in possession of HSV vectors encoding GM-

CSF prior the earliest effective filing date of Rabkin et al. Therefore, since Rabkin et al. qualifies as prior art over the claimed species of HSV, the rejection of record stands.

### ***Claim Objections***

The objection to claim 16 is withdrawn in view of the cancellation of this claim. It is noted that new claim 34, presented to replace claim 16, recites the EGR-1 promoter.

### ***Double Patenting***

Applicant is again advised that should claim 12 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant is further advised that should claim 8 be found allowable, claim 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your



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application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.